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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/671,816	09/25/2003	Vernon G. Wong	440882000201	6866

7590 07/27/2006

Stephen Donovan Esq.
2525 Dupont Dr., Mailstop T2-7H
Irvine, CA 92614

EXAMINER	
HAWES, PILI ASABI	
ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 07/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/671,816	WONG ET AL.	
	Examiner	Art Unit	
	Pili A. Hawes	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 March 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *35,37-39,42-47,51,52,55,56,61-67 and 82-92* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *35,37-39,42-47,51,52,55,56,61-67 and 82-92* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Receipt is acknowledged of applicant's Amendment/Remarks filed 03-24-2006.

MAINTAINED REJECTIONS

2. Upon further review the rejections made in the previous office action 07-11-2005 are re-presented and maintained:

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Previously present claims 35, 37-39, 42-47, 51, 52, 55, 56, 61-67 and 82-92 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wong et al. (USPN 5,869,079).

7. Wong et al. teaches an implant for treating inflammation of the eye (column 3, lines 65-67) including dexamethasone, a steroidal anti-inflammatory agent, and polylactic acid/polyglycolic acid copolymer (PLGA), a bioerodible copolymer without a release modifier in example 1 of the patent. More specifically, Wong et al. teaches implants particularly for use in the treatment of human (column 1, line 42) ocular conditions, diseases, tumors and disorders (column 6, lines 27-29) including uveitis (column 5, line 7). It should be noted, however, that the instant claims are product

claims and any intended use such as treatment of particular ocular conditions including uveitis does not alone show patentable distinction. If the prior art structure is capable of performing the intended use, then it meets the claim. Wong et al. also teaches various suitable implantable sites including the vitreous cavity (column 6, lines 29-35). Wong et al. teaches other anti-inflammatory steroids including hydrocortisone, cortisone, prednisolone, prednisone, however, dexamethasone is of particular interest (column 3). In addition, Wong et al. teaches the amount of the agent to be within the range of at least about 1 weight percent and usually no more than about 80 weight percent (column 4, lines 16-18) and furthermore exemplifies 50 percent dexamethasone in example 1. The agent weight percent limitations of claims 42-43, 61-63 of the application fall within the aforementioned range and are therefore satisfied by the teachings of Wong et al. The patent also teaches polyesters specifically, among bioerodible polymers (column 5, line 57). Additionally, Wong et al. also teaches fabricating monolithic implants (column 5, lines 19-24) by means of extrusion (example 1) into various shapes including particles, sheets, patches, plaques, fibers, and microcapsules (column 5, lines 16-18). Lastly, Wong et al. also teaches that an implant can be formulated to release an active agent over a period of at least about 3 days, usually at least about 1 week, and not more than about 1 year, usually not more than about 3 months (column 4, lines 59-63). Wong et al. also teaches specifically a time frame of about 4 to 6 weeks for the treatment of uveitis (column 5, lines 7-8). Wong et al. also teaches that the size and form of the implant can be used to control the rate of release, period of treatment, and drug concentration (column 7, lines 52-54).

8. Wong et al. does not teach the exact formulations and rates of release described in claims 35, 39, 52, 62-67 of the application, however it would have been obvious to someone skilled in the art through routine experimentation to optimize formulations by changing the size and form of the implant as suggested by Wong et al. (columns 7-8). A person of ordinary skill in the art would have been motivated to make such modifications because different ocular conditions call for different medicaments and different dosages of said medicaments. The expected result would be several formulations of implants, each formulation made for a specific ocular inflammation-mediated condition. Thus, the teachings of Wong render the instant claims obvious.

Response to Arguments

9. Applicant's arguments filed 4/13/2005 and 03-24-2006 have been fully considered but they are not persuasive. Applicant argues that:

a. The prior art does not disclose, teach, or suggest all of the elements recited in the present claims.

b. There is a lack of motivation for one of ordinary skill in the art to modify the specific amounts of the anti-inflammatory agent in Wong.

10. It is the position of the examiner that the prior art does teach and/or suggest all of the elements recited in the present claims as shown in the above paragraphs 3-10 of the rejection. In addition, the future intended use cannot impart patentability to a product. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is

capable of performing the intended use, then it meets the claim. Wong includes the claimed elements and also suggests varying the size and form of the implant in order to control the rate of release, period of treatment, and drug concentration (column 7, line 52 – column 8, line 3). Additionally, column 5, lines 15-18, provide the motivation one of ordinary skill in the art would need to modify the structure of the implant, as the reference teaches multiple structures and sizes can be chosen to be compatible with the selected site of insertion. The applicants amendment of the claims requiring the implant structure to be an extruded filament is rendered obvious by the prior art teaching. Not only does Wong suggest ways in altering the implant, one of ordinary skill in the art would have been able to optimize the formulation through routine experimentation. Thus, the prior art meets the limitations of the claims. For the aforementioned reasons, applicant's remarks are not persuasive.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pili Hawes whose telephone number is 571-272-8512. The examiner can normally be reached on 8:00 am - 5:00 pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Gollamudi S. Kishore, PhD
Primary Examiner
Group 1600

P. A. Hawes
Examiner-1615